

### REMARKS

Upon entry of the present amendments, claims 1, 29, and 32 will be pending in the application. Claims 2-28, 30-31, and 33-43 have been cancelled. New claims 44-46 have been added. Support for these claims was in the claims as originally filed. No new matter has been added.

#### Rejections under 35 USC 112, first paragraph – Written Description

Claims 1-4, 23, 24, 29, 32, 35, and 42 have been rejected for lack of written description. According to the Examiner, the specification fails to provide adequate written description for allelic variants of SEQ ID NO:2, variants which are the translation of a single nucleotide polymorphism, or variants which have any conservative amino acid substitution. The Examiner also asserts that the specification fails to provide a sufficient description of a protein with the amino acid sequence of SEQ ID NO:2 because it fails to provide a description for any of the structural, physical, or biological properties of the protein. *See* Office Action at page 4. Applicants traverse.

In order to facilitate prosecution, and without acceding to the propriety of the Examiner's position, Applicants have cancelled claims 2-4 and 23-24. Claims 2-4 were directed to allelic variants, single nucleotide polymorphic variants, or variant polypeptides consisting of conservative amino acid substitutions. Claims 23-24 were directed to a method of treatment. Because these claims have been canceled, the rejections with respect to claims 2-4 and 23-24 have been rendered moot.

Applicants submit that pending claims 1, 29, 32, and 44-46 meet the written description requirements for the following reasons. . New claims 44-46 recite a polypeptide consisting of SEQ ID NO:2. A recitation of the sequence of amino acids of SEQ ID NO:2 is disclosed in the specification at page 12, lines 23-25. Accordingly, applicants submit that new claims 44-46 meet the written description requirement.

Claim 1 is directed to an isolated polypeptide comprising an amino acid sequence of SEQ ID NO:2. This claim is the same type of claim used as an example in the USPTO Training Materials for Written Description Guidelines. Example 13 of these Training Materials recites

“An isolated protein having SEQ ID NO:3.” In the guidelines, Examiners are instructed to find that claims of this type satisfy written description for the following rationale. Instant claim 1 is directed to a genus of proteins that comprise SEQ ID NO:2. One member of the genus, SEQ ID NO:2, is described by a complete structure. There is relatively little variation among the species within the genus because each member of the genus shares SEQ ID NO:2 as a necessary common feature. As stated in the guidelines, “The single disclosed example is representative of the claimed genus because taken in view of the general knowledge in the art, the disclosure is sufficient to show that one of skill in the art would conclude that applicant was in possession of the claimed genus.” See Synopsis of Application of Written Description Guidelines at Example 13, page 51. Therefore, applicants respectfully submit that the subject matter of claim 1 is adequately described. Likewise, the subject matter of claims 29 and 32 is adequately described in the specification. Claim 29 is directed to a pharmaceutical composition of the polypeptide of SEQ ID NO:2, and is supported by disclosure at page 59, line 20 through page 63, line 14 of the specification. Claim 32, is directed to a kit of the pharmaceutical composition, and is supported by disclosure at page 63, lines 15-16 of the specification. Applicants respectfully request that the written description rejections of claims 1, 29 and 32 be withdrawn.

Rejections under 35 USC 112, first paragraph – Enablement

Claims 1-4, 23-24, 29, and 32 have also been rejected as lacking sufficient disclosure to enable one skilled in the art to make and use the invention as claimed. According to the Examiner, the specification fails to provide sufficient guidance as to the structural and biological properties of SEQ ID NO:2 or naturally occurring allelic variants of SEQ ID NO:2. The Examiner further asserts that the specification fails to identify amino acid residues or nucleotides that are crucial or non-essential for biological activity, fails to provide any specific evidence that SEQ ID NO:1 encodes a protein corresponding to SEQ ID NO:2 or to provide guidance as to the biological activity of SEQ ID NO:2. Applicants traverse.

One skilled in the art would be able to make and use the invention as claimed. As mentioned previously, the claims directed to variants of SEQ ID NO:2 have been cancelled. The relation between the sequence of bases in DNA and the sequence of amino acids in proteins is

well established. Thus, Applicants assert that one of ordinary skill in the art would recognize that SEQ ID NO:1 encodes a protein corresponding to SEQ ID NO:2.

The Examiner concedes that “the office has not made a rejection of the claims under 35 U.S.C. 101 for lack of utility.” Office Action at page 7. The specification discloses that SEQ ID NO:2 is highly homologous to members of the prothymosin gene family. *See* Specification at page 13, lines 1-5. The existence of this homology to the family demonstrates that SEQ ID NO:2 is a novel member of the prothymosin  $\alpha$  family. Accordingly, one skilled in the art would recognize that the disclosed sequence of the polypeptide of the present invention, as a member of the prothymosin  $\alpha$  family, can be expected to function as an immunomodulatory molecule.

According to the Examiner, the specification also fails to provide any guidance as to the pathologies or diseases associated with SEQ ID NO:2. Applicants have cancelled claims 23 and 24, which were directed to methods of treating or preventing a pathology associated with the polypeptide of SEQ ID NO:2.

For the reasons recited above, Applicants assert that the application meets the enablement requirements, and this rejection should be withdrawn.

Rejections under 35 USC 112, second paragraph

Claims 1-4, 23-24, 29, and 32 were rejected under 35 USC 112, second paragraph as being indefinite. According to the Examiner, since the limitations of claims 2-4 contradict the limitations of claim 1, the metes and bounds of claims 1-4, and claims 23-24, 29, and 32, which depend from claim 1, cannot be determined. Claims 2-4 have been cancelled herein. Thus, Applicants contend that the metes and bounds of claim 1 can be determined. Claims 23 and 24 have also been cancelled. Claims 29 and 32 do not contain any limitations that contradict the limitations of claim 1. Therefore, claims 1, 29, and 32 are clear and definite. Thus, Applicants request that this rejection be withdrawn.

### CONCLUSION

On the basis of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A petition for a one-month extension of time accompanies this response. The Commissioner is authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 15966-572.

Respectfully submitted,

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